

EXHIBIT 29

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April 24, 2018

The Honorable Greg Walden
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515-6115

The Honorable Frank Pallone, Jr.
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515-6115

Re: McKesson Corporation

Dear Chairman Walden and Representative Pallone:

I am writing on behalf of McKesson Corporation¹ to provide the Committee with additional information, in response to your letter dated February 15, 2018 (“Letter Request”), which asked for certain information and documents related to McKesson’s operations in West Virginia between 2005 and the present. As you know, we produced documents responsive to those requests last week. Below we respond to questions posed in your Letter Request.

In some instances, the Committee’s requests concern events that occurred more than a decade ago. McKesson has exercised its best efforts to gather and reconstruct information responsive to those requests, but if further, clarifying information is obtained in the future, the company may supplement its responses.

I. History of McKesson’s Controlled Substance Monitoring System

The Letter Request asks several questions about McKesson’s Controlled Substance Monitoring Program (“CSMP”) as it existed at various points in time during the last 12 years. Set forth below is a description of McKesson’s CSMP as it evolved over

¹ McKesson U.S. Pharmaceutical is the business unit of McKesson Corporation that is relevant to the requests contained in the Committee’s February 15 letter. Accordingly, the responses contained in this letter are based on information provided by McKesson U.S. Pharmaceutical. Throughout this letter, McKesson U.S. Pharmaceutical is referred to as “McKesson” or the “Company.”

COVINGTON

The Honorable Greg Walden
The Honorable Frank Pallone, Jr.
April 24, 2018
Page 2

time in response to industry guidance provided by DEA, direct interactions between the Company and the agency, and initiatives undertaken by the Company.

A. Pre-2008 Monitoring Program

For a number of years prior to 2008, McKesson complied with DEA's suspicious order reporting regulation (21 C.F.R. § 1301.74(b)) by submitting reports to local DEA offices that listed shipped orders that exceeded certain predetermined quantities. We understand that this was a common practice throughout the industry. The reports were large hard copy printouts of individual orders. During this time period, DEA personnel often referred to these reports as "excessive order" reports.

In 2006 and 2007, DEA began to focus on the proliferation of internet pharmacies which, although registered with DEA, were dispensing increasing amounts of controlled substances. DEA was aware of this trend based on the monthly/quarterly ARCOS reports being provided to DEA by the regulated industry. In connection with investigation and enforcement challenges presented by those pharmacies, DEA provided the industry with general guidance about the obligations of distributors to also report suspicious orders and to maintain effective controls against diversion. More specifically, DEA sent letters to the industry in September 2006 and February 2007 that addressed its view of the obligation of distributors to report suspicious orders. In December 2007, DEA sent a third letter to the industry which stated that, in the view of the agency, the identification of excessive orders was insufficient to meet distributors' regulatory obligations to report suspicious orders to DEA.

During this same time period, McKesson was engaged in active discussions with DEA about its distribution center in Lakeland, Florida, with respect to internet pharmacies. Following a series of meetings with McKesson in early 2006, DEA issued an order to show cause in August 2006 concerning the Lakeland distribution center's DEA registration. McKesson met regularly with DEA throughout 2007 in an effort to resolve issues raised by the show cause order.²

During 2006 and 2007, McKesson reviewed, and developed enhancements to, its compliance program. In May 2007, McKesson implemented a new controlled substance monitoring program across its U.S. Pharmaceutical distribution centers. In a letter to

² In September 2007, DEA executed an administrative inspection warrant at McKesson's distribution center in Conroe, Texas. The following month, DEA issued a show cause order with respect to McKesson's Landover, Maryland distribution center. McKesson's discussions with DEA included issues related to these two distribution centers, in addition to the issues raised previously with respect to the Lakeland, Florida distribution center.

COVINGTON

The Honorable Greg Walden
The Honorable Frank Pallone, Jr.
April 24, 2018
Page 3

DEA dated April 25, 2007, McKesson outlined the key elements of the program and provided specific details about the planned operation of the program. In June 2007, McKesson provided DEA with copies of the program manual, including a training presentation given on the program at McKesson's National Operations Conference in April 2007.³

As the Company informed DEA, McKesson's program monitored orders for four specific controlled substances: hydrocodone, oxycodone, alprazolam, and phentermine, which were specific substances of concern identified by DEA at that time. Using daily dosage summary reports, McKesson identified pharmacies that had placed orders that exceeded a monthly threshold of 8,000 doses. These customers and the orders were subject to further review by McKesson. McKesson's program manual provided for a three-level escalating review system to conduct an evaluation when a customer exceeded its monthly threshold for any of these four controlled substances. The three levels of review that existed at that time are described below:

- Level I: The first level of review involved an analysis of previous purchases by the pharmacy. At this stage of the review process, McKesson's evaluation could include internet research on the pharmacy and interviews of the account representative responsible for the pharmacy. In some cases, McKesson's program contemplated telephonic interviews of the pharmacy owner to learn more about the circumstances surrounding the amounts that had been ordered. If McKesson was unable to conclude through this initial evaluation that the orders were reasonable or the review was inconclusive, McKesson was required to conduct a second level of review.
- Level II: Under the terms of McKesson's program manual, the second level review required a physical site visit to the pharmacy. During the site visit, the manual required McKesson to conduct an in-person interview of the owner using a standard questionnaire. McKesson personnel were also required to review relevant documentation during the site visit. If, after conducting a review, McKesson resolved the outstanding issues, that determination was required to be documented and included in the files maintained for the pharmacy in question. If the results of the Level II review were still inconclusive, the program manual required a third level of review.

³ Copies of the April 25, 2007 letter to DEA, the program manual, and the August 2007 training presentation have been produced to the Committee.

COVINGTON

The Honorable Greg Walden
The Honorable Frank Pallone, Jr.
April 24, 2018
Page 4

- Level III: As provided in the program manual, the Vice President of the Regulatory Affairs department was responsible for the third level of review. Depending on the circumstances, this level of review could involve senior management and consultation with the legal department. The program manual also contemplated contact with local DEA and DEA headquarters, under certain circumstances, based on decisions related to the discontinuation of sales to the customer.

B. The 2008 Controlled Substance Monitoring Program

In 2008, McKesson finalized its settlement with DEA concerning the 2006 show cause order and related issues. During the final stages of the settlement negotiations, McKesson had a number of meetings with DEA. Among the items addressed at those meetings was McKesson's controlled substance monitoring program. DEA emphasized to McKesson that the Company needed to focus on knowing its customers. Moreover, certain local DEA offices communicated to McKesson that it should stop sending "excessive order" reports because they were inundating the local DEA office fax machines and were not useful. From these meetings with DEA, and other communications from local DEA offices, McKesson understood that DEA was no longer interested in receiving "excessive order" reports pursuant to DEA's suspicious order reporting regulation. Instead, rather than focusing on individual orders that exceeded specified quantities, McKesson believed that DEA wanted the Company to identify problematic pharmacies and report those pharmacies to DEA. Accordingly, McKesson revised its monitoring program to focus on identifying suspicious customers and reporting those customers to DEA. While orders that exceeded monthly thresholds were blocked under the program, those blocked orders were not reported to DEA as "suspicious."

On July 31, 2008, McKesson representatives met with DEA personnel at DEA Headquarters to explain the details of the CSMP. At the meeting, McKesson representatives made a slide presentation to DEA which provided a detailed overview of the program.⁴ The presentation covered the core elements of the CSMP, including the focus on knowing the customer, as recommended by DEA, and a revised three-level review process. McKesson's presentation also described in detail the establishment of a monthly order threshold system, which, for the first time, would block any order for a specified controlled substance that exceeded a monthly threshold. Importantly, McKesson's presentation described the Company's plan to focus on the reporting of suspicious customers to DEA following the three-level review process.

⁴ A copy of the slide presentation provided to DEA on July 31, 2008 has been produced to the Committee.

COVINGTON

The Honorable Greg Walden
The Honorable Frank Pallone, Jr.
April 24, 2018
Page 5

In the fall of 2008, as contemplated by the settlement documents, DEA conducted a number of site visits to certain McKesson distribution centers to review compliance with DEA requirements. The DEA's site visits also included a review of McKesson's revised CSMP. As set forth in the settlement documents, DEA conducted these site visits as a condition of lifting the suspensions of the DEA registrations for several McKesson distribution centers. At the completion of those reviews, DEA lifted the suspensions of the registrations for those distribution centers. DEA does not appear to have raised any concerns about the program's design or its focus on suspicious customers at that time.

Below is a summary of the elements of the CSMP that McKesson reviewed with DEA during the July 31, 2008 meeting and the various distribution center site visits.

1. Enhanced Customer Diligence

McKesson's CSMP established standardized procedures for customer diligence. For example, new pharmacy customers were required to submit a questionnaire that called for information about the pharmacy's purchase history, background, and business. The CSMP also provided for customer site visits, which could include on-site interviews. During a site visit, McKesson personnel were expected to observe, among other things, whether customer traffic appeared to be consistent with the pharmacy's business type and overall volume. Directors of Regulatory Affairs were responsible for analyzing the questionnaires and supporting documentation and making determinations about whether new customers were eligible to purchase controlled substances.

2. Monthly Purchasing Thresholds

As part of the CSMP, McKesson implemented an order management system that assigned each pharmacy monthly thresholds for orders of controlled substances. Each month, under this system, a pharmacy's orders for controlled substances were monitored against the applicable thresholds. If an order exceeded an established monthly threshold, the order was automatically blocked and not shipped to the pharmacy. If an order was blocked because it exceeded the applicable threshold, the customer would be unable to order any additional products from the category or family of controlled substances (referred to as a "DEA base code") until the following month.

COVINGTON

The Honorable Greg Walden
The Honorable Frank Pallone, Jr.
April 24, 2018
Page 6

Since its implementation in 2008, McKesson's threshold management system has blocked over a million orders for controlled substances.⁵ McKesson does not ship orders that exceed thresholds.

3. Three-Level Review

McKesson's CSMP also implemented a revised three-level review process to evaluate pharmacies whose orders exceeded monthly thresholds. As provided by the CSMP, during the first level of review, McKesson personnel were required to contact the pharmacy to determine the reason why the applicable threshold had been reached. They were authorized to conduct additional analysis as appropriate. If the evaluation conducted during the first level of review was inconclusive, the review was escalated to Level II.

During the second level of review, McKesson's regulatory affairs team was expected to conduct additional diligence to determine whether the pharmacy's ordering was appropriate. The second level of review could include a site visit, a customer interview, and other investigation or analysis as appropriate.

If the results of the second level of review raised issues of concern, the matter was required to be escalated to Level III. Once a matter reached Level III, McKesson blocked the pharmacy's ability to order controlled substances and the matter was required to be escalated to the Senior Vice President of Distribution Operations, among others, for review.

4. Reporting Suspicious Customers to DEA

Upon completion of the three-level review process, McKesson reported terminated customers to DEA Headquarters.

C. McKesson's Post-2013 CSMP

In 2013, McKesson devoted substantial resources to enhance and revise its CSMP. Over the past five years, McKesson has made a number of key enhancements to its policies and procedures, strengthened its compliance team, increased its customer due diligence efforts, enhanced its ongoing oversight processes, and provided additional customer education. McKesson has also devoted substantial resources to the

⁵ McKesson's threshold management program has blocked and not filled more than 13,000 orders of controlled substances in West Virginia, including more than 6,000 orders for oxycodone and hydrocodone products. A spreadsheet listing this information has been produced to the Committee.

COVINGTON

The Honorable Greg Walden
The Honorable Frank Pallone, Jr.
April 24, 2018
Page 7

development and implementation of advanced threshold analytics to monitor and control the distribution of controlled substances. McKesson's CSMP applies to all distributions of controlled substances from each of its U.S. Pharmaceutical distribution centers across the country. The key elements of McKesson's revised CSMP are summarized below.

1. Expanded Compliance Team

In order to further strengthen its compliance program, McKesson has added a number of subject matter experts to its CSMP team. McKesson's team now includes individuals with more than 240 years of cumulative DEA enforcement experience. In addition to hiring former DEA agents and diversion investigators, McKesson has hired industry experts with experience in the retail pharmacy industry, experience as state and board of pharmacy investigators, experience with pharmaceutical manufacturers, and experience with data analytics. McKesson believes that its current CSMP team is among the strongest in the industry.

2. Customer Due Diligence

McKesson performs comprehensive due diligence on prospective pharmacy customers before agreeing to supply controlled substances. McKesson requires all independent retail pharmacies that are prospective customers to complete a detailed questionnaire, provide three months of dispensing data for analysis, undergo a site visit, and provide copies of all licenses.⁶

3. Advanced Threshold Analytics and Suspicious Order Reporting

McKesson has also expended significant resources to implement a cutting-edge controlled substances threshold management program, using complex data analytics to set and manage individual customer thresholds for certain controlled substances. McKesson's model analyzes each customer order against established monthly thresholds to determine whether that order should be filled. If a customer's order exceeds the monthly threshold, that order is required to be blocked and not filled. McKesson reports each blocked order to DEA pursuant to 21 C.F.R. § 1301.74 and to state monitoring agencies pursuant to applicable state reporting regulations, including the West Virginia Board of Pharmacy.

⁶ McKesson's current CSMP does not use IMS Health market reports as part of its customer diligence process or in the setting of thresholds.

COVINGTON

The Honorable Greg Walden
The Honorable Frank Pallone, Jr.
April 24, 2018
Page 8

4. Ongoing Oversight

As part of McKesson's customer monitoring process, pharmacies can be subjected to a complete due diligence examination that may include an analysis of their purchase data for red flags, licensing verification, and open-source searches for adverse information about the pharmacy. McKesson's pharmacy reviews may also include an analysis of customer-provided aggregate dispensing data.

5. Customer Education

McKesson has been proactive with respect to educating its customers about the importance of compliance with DEA and state agency regulations. McKesson educates customers and provides them with literature on how to identify the warning signs of prescription abuse and diversion. Similarly, McKesson trains and educates its own employees on the company's regulatory obligations, including CSMP-specific training sessions at annual sales meetings. Nearly 600 McKesson employees have been trained on the CSMP so far.

6. Collaboration with Federal and State Authorities

McKesson is an active participant in state and federal efforts to address the diversion and abuse of controlled substances. The company strongly supports calls for additional formal and continuing medical education on the dangers of opioid use as important ways to curb clinically inappropriate prescribing, doctor shopping, abuse and diversion. McKesson has published two whitepapers outlining a series of initiatives aimed at alleviating the impact of the opioid crisis.⁷

II. West Virginia Pharmacies

In the Letter Request, the Committee asks a number of questions about two West Virginia pharmacies: Sav-Rite Pharmacy in Kermit and Family Discount Pharmacy, with locations in Mount Gay-Shamrock and Stollings. Below is a summary of what McKesson has learned about these pharmacies from its review of available information.

A. Sav-Rite Pharmacy

According to available sales data, McKesson supplied Strosnider Drug, d/b/a Sav-Rite Pharmacy ("Sav-Rite") from February 2006 through November 2007.⁸ Sav-

⁷ Copies of these whitepapers have been shared with the Committee.

⁸ Data on sales prior to February 2006 is not available.

COVINGTON

The Honorable Greg Walden
The Honorable Frank Pallone, Jr.
April 24, 2018
Page 9

Rite was located on U.S. Highway 52 in Kermit, West Virginia, and was owned by James Wooley. Prior to 2006, D&K Healthcare Resources, Inc., a regional distributor, supplied Sav-Rite with controlled substances. McKesson acquired D&K Healthcare Resources, Inc. in late 2005, and Sav-Rite became a McKesson customer through this acquisition.

As the data provided in McKesson's document production show, Sav-Rite placed very large orders for hydrocodone and oxycodone after becoming a McKesson customer in 2006. In November 2007, as a result of a review initiated under McKesson's monitoring program, McKesson *terminated* Sav-Rite's ability to purchase controlled substances. McKesson made the decision to terminate Sav-Rite following a November 14, 2007 site visit to the pharmacy and a visit to a nearby medical clinic where many of the prescriptions filled by the pharmacy were written. Prior to the site visit, McKesson had conducted an analysis of Sav-Rite's purchase data and identified the pharmacy for further investigation. McKesson never resumed selling controlled substances to Sav-Rite while Sav-Rite was owned by James Wooley.

In the fall of 2011, Steven Williams purchased Sav-Rite Pharmacy and began operating the pharmacy under the name Medicine Cabinet Pharmacy. For a short period of time following the transaction, Medicine Cabinet pharmacy used Sav-Rite's DEA registration number, under a power of attorney, until Medicine Cabinet obtained a new DEA registration number in its own name. Accordingly, to the extent that ARCOS data obtained by the Committee shows sales in late 2011 and early 2012 to Sav-Rite Pharmacy, McKesson's records indicate that those sales were to Medicine Cabinet Pharmacy, owned by Steven Williams.

B. Family Discount Pharmacy (Mount Gay)

In the Letter Request, the Committee included a table that listed McKesson's sales to the Family Discount Pharmacy in Mount Gay during the period from 2006 through 2014 and asked a series of questions about the history of McKesson's business relationship with this pharmacy. As reflected in that table, McKesson did not sell the Family Discount Pharmacy in Mount Gay any oxycodone or hydrocodone products in 2008, 2009 and 2011 and, compared to other years, a significantly smaller quantity of those products in 2010. McKesson has conducted a diligent search of its records and has not located a due diligence file for 2008 and 2009. In an e-mail to DEA on February 6, 2009, McKesson provided the agency with a list of pharmacies that had been terminated for compliance reasons. McKesson included Family Discount Pharmacy in Mount Gay on this list. Based on this e-mail, McKesson believes that the lack of sales in 2008 and 2009 can be attributed to a decision to terminate Family Discount Pharmacy in Mount Gay as a customer.

COVINGTON

The Honorable Greg Walden
The Honorable Frank Pallone, Jr.
April 24, 2018
Page 10

In September 2012, McKesson conducted its onboarding process and reinstated the Family Discount Pharmacy in Mount Gay as a customer. As part of the due diligence conducted by McKesson during the onboarding process, McKesson contacted the West Virginia Board of Pharmacy to inquire as to whether there was any information that would inform McKesson's decision to accept this pharmacy as a customer. The West Virginia Board of Pharmacy reported that this pharmacy was a reliable high volume account, noting that the pharmacy may have had an issue a long time ago, but according to the West Virginia Board of Pharmacy that issue had been resolved and was a reliable pharmacy.

McKesson's experience in 2013 confirmed the West Virginia Board of Pharmacy's view that Family Discount Pharmacy in Mount Gay was a "high volume account." In 2013, the pharmacy ordered more than 6.9 million doses of *non*-controlled substances compared to 2.06 million doses on average for all other McKesson non-chain, retail pharmacy customers in West Virginia who also had orders for controlled substances. During its time as a McKesson customer, Family Discount Pharmacy in Mount Gay was consistently one of the larger retail purchasers of non-controlled substances in West Virginia.

In March 2014, following a request by the pharmacy for an increase in its monthly threshold for alprazolam, McKesson's regulatory affairs team conducted a standard diligence review of the customer in accordance with the CSMP. This review included an analysis of Family Discount Pharmacy's purchases from McKesson, a review of dispensing data acquired from the pharmacy, and a site visit by one of McKesson's regional Directors of Regulatory Affairs. The review of Family Discount Pharmacy's dispensing data indicated that, while the pharmacy used McKesson as its primary wholesaler, the pharmacy was dispensing more hydrocodone than was delivered by McKesson. For the four month period between December 2013 and March 2014, the pharmacy dispensed approximately 11,000 more doses of hydrocodone monthly than had been purchased from McKesson. As part of the investigation, McKesson's regulatory affairs team determined that Family Discount Pharmacy was also filling prescriptions from physicians who had been identified by another McKesson customer as potentially having questionable prescribing patterns. Based on the information obtained during this review, in April 2014, McKesson chose to stop selling controlled substances to Family Discount Pharmacy in Mount Gay.⁹

C. Family Discount Pharmacy (Stollings)

The Family Discount Pharmacy of Stollings was a McKesson customer during the period from 2006 until mid-2010. It appears that Family Discount Pharmacy of

⁹ The investigative report for this review has been produced to the Committee.

COVINGTON

The Honorable Greg Walden
The Honorable Frank Pallone, Jr.
April 24, 2018
Page 11

Stollings utilized one or more other distributors from mid-2010 to fall 2012. At or about the same time that McKesson reinstated Family Discount Pharmacy in Mount Gay as a customer in 2012, McKesson conducted an onboarding diligence review, pursuant to the CSMP, for the Family Discount Pharmacy of Stollings. After the completion of this process, McKesson onboarded Family Discount Pharmacy of Stollings as a customer in October 2012. In 2013, the Family Discount Pharmacy of Stollings ordered approximately 3.1 million doses of *non*-controlled substances, or approximately a million doses of *non*-controlled substances more, on average, than all other McKesson non-chain, retail pharmacy customers in West Virginia that also ordered controlled substances during the same time period.

In August 2015, McKesson conducted a proactive review of the Stollings location. As part of this review, a member of McKesson's regulatory affairs team visited the pharmacy and required the pharmacy to complete an updated questionnaire. McKesson also obtained recent dispensing data from the pharmacy and conducted an analysis of that data. The review conducted by McKesson's regulatory affairs team revealed no issues with the Family Discount Pharmacy of Stollings. Accordingly, McKesson made no changes to the pharmacy's thresholds or ability to purchase controlled substances.¹⁰

In early 2016, the Family Discount Pharmacy of Stollings chose to leave McKesson for another distributor. McKesson believes that Family Discount Pharmacy made this decision because McKesson would not agree to reinstate the Mount Gay location's ability to order controlled substances.

McKesson appreciates this opportunity to respond to the Committee's questions. Please let us know if you require additional information.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'R. Kelner', with a long horizontal flourish extending to the right.

Robert K. Kelner

¹⁰ The investigative report for this review has been produced to the Committee.